



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1338d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

June 1, 2001

VIA FACSIMILE

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

WARNING LETTER

Charles Lehman, President
Lehman Foods, Inc.
8329 De Celis Place
North Hills, CA 91343

W/L 51-01

Dear Mr. Lehman:

During an inspection of your manufacturing facility, Café St. Clair, Inc. located at 1433 Miller Drive, Colton, CA conducted May 14 and 15, 2001, we found that you manufacture and distribute ready to eat food products, including pre-packaged sandwiches, under the following labels:

Café St Clair, Distributed by LEHMAN FOODS INC.
and FRESH TO YOU Classico, Distributed by Canteen Corp.

During the inspection, we collected a number of samples including unopened ingredients, sliced meats and cheeses, and finished products. Our analysis of these samples revealed *Listeria monocytogenes* (*L. mono*) contamination as follows:

1. We isolated *L. mono* from finished retail units of turkey and cheddar cheese submarine sandwiches (FDA Sample Number 133746) and turkey, ham and cheese submarine sandwiches (FDA sample number 133745).
2. We isolated *L. mono* from ham (FDA Sample Number 133739), cheddar cheese (FDA Sample Number 133740) and provolone cheese (FDA Sample Number 133741) which were sliced at your facility to be used in the preparation of your finished sandwiches.
3. Our analysis of bulk, unopened units of ham (FDA Sample Number 133742), cheddar cheese (FDA Sample Number 133743) and provolone cheese (FDA

Sample Number 133744), in storage at your facility, showed no *L. mono* contamination.

Listeria monocytogenes is a pathogenic organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women. Therefore, the products listed in items 1. and 2. above are adulterated under section 402(a)(1) of the Food, Drug and Cosmetics Act (the Act) because they are contaminated with the pathogenic bacteria *Listeria monocytogenes* which may render the product injurious to health. We note that you are conducting a recall of products from the marketplace and acknowledge your action in this regard.

We further note that the U. S. Army notified you in May 2001 that they had isolated *L. mono* from your ham and turkey and turkey and cheddar sandwiches sampled in April 2001. You were also recently notified that *L. mono* was isolated from several other sandwiches collected by the U. S. Army in May 2001, including your ham and cheese, ham and turkey, pastrami and cheese, french dip, roasted turkey croissant, tuna salad croissant, chicken pesto pita, tuna pita and turkey pita. The repeat nature of the *Listeria monocytogenes* contamination of your food products, as evidenced by the U. S. Army and FDA test results, along with the negative sample results associated with the incoming food ingredients used to manufacture your products, indicates that you have a widespread problem with *Listeria monocytogenes*.

In addition, we also observed inappropriate food handling and sanitation practices as outlined at the conclusion of the inspection on the Form FDA-483 issued to Cary Thomas. Based on these insanitary practices, along with the U. S Army test results from April and May 2001, and the FDA sample results describing *Listeria monocytogenes* contamination of your sandwiches described above, we regard all products prepared, packed, or held at your facility to be adulterated within the meaning of Section 402(a)(4) of the Act.

Among the significant findings described on the Form FDA – 483 is the observation that the temperature of your cold storage room fluctuated from 48° to 50° F from 11:30 a.m. to 3:30 p.m. on May 14, 2001. This high temperature may not prevent the rapid growth of undesirable microorganisms. Test results supplied to you by the U. S. Army in May 2001 indicate that some of your products are not only contaminated with *L. mono*, but also have high levels of aerobic bacteria (>600,000,000 cfu/g), coliforms (50, 000 cfu/g) and/or *E. coli* (up to 11,000 cfu/g), which are further indications of insanitary practices and/or conditions at your facility.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act.

Letter to Mr. Lehman

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Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Additionally, due to the serious concerns we have over the repeat nature of the *Listeria* contamination, we request that you contact this office to schedule a meeting within five (5) days of receipt of this letter. You may schedule this meeting by calling the district office at 949-798-7714 and arranging a mutually agreeable date and time.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse", followed by the typed text "A. D. D. For".

Alonza E. Cruse
District Director

cc: Carey Thomas
Café St. Clair
Vice President, Operations
1433 Miller Drive
Colton, CA 92324

